REMARKS

In the Office Action, claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,846,195 to Alt.

In the Office Action, claims 4-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,846,195 to Alt in view of U.S. Patent No. 6,104,949 to Pitts Crick et al.

In the Office Action, claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,846,195 to Alt.

In response thereto, claims 1-14 and 36 have been cancelled. Accordingly, claims 15-35 are now pending. Following is a discussion of the patentability of each of the pending claims.

Independent Claim 15

Claim 1 recites an implantable cardiac device comprising circuitry to sense whether a patient is in intrinsic rhythm when transitioning from a less upright posture to a more upright posture, and a processor to promote intrinsic rhythm of the patient's heart by (i) in an event that the circuitry senses the patient is not in intrinsic rhythm, applying increased pacing to counter effects of orthostatic hypotension caused by the transition from the less upright posture to the more upright posture and (ii) in an event that the circuitry senses the patient is in intrinsic rhythm, disabling increased pacing for a programmed duration.

In accordance with the specification of the present application, it is believed that by virtue of being in intrinsic rhythm, even though slow, the natural variation in rate and/or the increase in heart rate during a postural change will allow for a more natural vasoconstrictive response, leading to reduced blood pressure drop. The transient blood pressure drop upon orthostatic stress, such as standing, correlates positively with consequent symptoms of orthostasis, such as dizziness and/or lightheadedness. Because of this correlation, there is reason to believe that reducing the transient blood

pressure drop upon orthostasis may also mitigate its symptoms, which afflict a significant percentage of pacemaker patients. As such, the implantable cardiac device of the present application is programmed to detect when a resting patient experiences a condition of non-rest, such as when the patient beings to sit up or stand after laying down for a prolonged period. If the patient's heart is in intrinsic rhythm, the device disables any increased pacing rate for a programmed duration, such as 5 to 120 seconds, to allow a more natural vasoconstrictive response.

The Alt reference discloses an implantable medical device having a sensor to detect the physical orientation of the implantable medical device within a patient, which is indicative of whether the patient is standing, sitting, or reclining. Column 6, lines 19-27 states that "... the desire is to provide a greater degree of control of the rate response of the cardiac pacemaker in which the sensor is housed such that the stimulation rate developed by the pacemaker tends to duplicate the normal heart rate that would be experienced by a healthy person under the same condition of the resting position of the body or of exercise." According to the Alt reference, this desire is achieved by having a pulse generator increase the pacing rate when the patient arises from a reclining position to an upright position. However, the Alt reference is silent on the desire to achieve a more natural vasoconstrictive response in order to mitigate the negative effects of orthostasis. In particular, the Alt reference does not disclose or suggest having a processor promoting intrinsic rhythm of a patient's heart by (i) in an event that the circuitry senses the patient is not in intrinsic rhythm, applying increased pacing to counter effects of orthostatic hypotension caused by the transition from the less upright posture to the more upright posture and (ii) in an event that the circuitry senses the patient is in intrinsic rhythm, disabling increased pacing for a programmed duration.

Furthermore, it is apparently conceded that the Alt reference does not disclose or suggest a processor to promote intrinsic rhythm of a patient's heart by (i) in an event that the circuitry senses the patient is not in intrinsic rhythm, applying increased pacing to counter effects of orthostatic hypotension caused by the transition from the less

upright posture to the more upright posture and (ii) in an event that the circuitry senses the patient is in intrinsic rhythm, disabling increased pacing for a programmed duration. For this reason, it appears the Examiner has introduced the Pitts Crick et al. reference. The Pitts Crick et al. reference is directed to a device using physiology to indicate congestive heart failure. In particular, the device senses trans-thoracic impedance, which is dependent on blood or fluid content of the lungs, to assist in the detection and quantification of pulmonary edema and thus congestive heart failure. The Alt reference further utilizes posture data to determine the degree of pulmonary edema because trans-thoracic impedance is affected by posture (whether the subject is lying down or standing up). In a healthy subject, when the subject lies down to sleep, the pulmonary veins are filled such that trans-thoracic impedance drops for short period at the onset. The trans-thoracic impedance quickly thereafter returns to the baseline value in accordance with Frank-Startling Law and because the left ventricular flow out of the lungs increases. In the morning (when the subject wakes and stand up), impedance rises briefly and thereafter returns to the baseline value. In a patient with mild heart failure, pulmonary congestion is present while the patient is lying down such that trans-thoracic impedance decreases and remains at its lower level throughout the night. At the end of the night, trans-thoracic impedance returns to its base line once the patient rises and is no longer lying down. In a patient with moderate congestive heart failure, transthoracic impedance may continue to decrease throughout the night because of the development of edema and return to its initial base line after the patient has risen. In a patient with severe congestive heart failure, impedance may remain low due to the persistence of pulmonary edema. As such, the Pitts Crick et al. reference provides a method and device for the diagnosis or treatment of congestive heart failure by correlating changes in posture with trans-thoracic impedance changes. Upon detection of congestive heart failure, the device delivers electrical stimulation and/or controls drug delivery.

The Pitts Crick et al. reference does not address the topic of allowing a more natural vasoconstrictive response to mitigate the negative effects of orthostasis. In particular, the Pitts Crick et al. reference does not disclose or suggest a processor to

promote intrinsic rhythm of a patient's heart by (i) in an event that the circuitry senses the patient is not in intrinsic rhythm, applying increased pacing to counter effects of orthostatic hypotension caused by the transition from the less upright posture to the more upright posture and (ii) in an event that the circuitry senses the patient is in intrinsic rhythm, disabling increased pacing for a programmed duration. In accordance with the Pitts Crick et al. reference, upon detection of the congestive heart failure, the device delivers electrical stimulation. Nowhere does the Pitts Crick et al. reference disclose a particular electrical stimulation therapy such as disabling increased pacing for a programmed duration.

Furthermore, the Final Office Action states that the Pitts Crick et al. reference teaches of a programmer that communicates with a programmer interface block to obtain data which is transferred to storage for use in analyzing system conditions, patient information, and changing the pacing conditions if warranted. It is respectfully submitted that "changing the pacing conditions if warranted" does not adequately disclose what is recited in claim 15 of the present application.

Accordingly, it is respectfully submitted that claim 15 is in condition for allowance.

Dependent Claims 16-19

Claims 16-19 depend from claim 15 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 20

For at least the same reasons discussed above with regards to claim 15, it is respectfully submitted that claim 20 is in condition for allowance.

Dependent Claims 21-24

Claims 21-24 depend from claim 20 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 25

For at least the same reasons discussed above with regards to claim 15, it is respectfully submitted that claim 25 is in condition for allowance.

Dependent Claim 26

Claim 26 depends from claim 25 and is similarly patentable. Accordingly, it is respectfully submitted that claim 26 is in condition for allowance.

Independent Claim 27

For at least the same reasons discussed above with regards to claim 15, it is respectfully submitted that claim 27 is in condition for allowance.

Dependent Claims 28-31

Claims 28-31 depend from claim 27 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 32

For at least the same reasons discussed above with regards to claim 15, it is respectfully submitted that claim 32 is in condition for allowance.

Dependent Claims 33-35

Claims 33-35 depend from claim 32 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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